Test Procedure

All specimens must be at room temperature before testing.

Expiration date: Check expiration date on each individual test package or outer box before using. Do not use any test past the expiration date on the label.

Disposable gloves and safety glasses are recommended when running this test. Wash hands thoroughly after handling any patient sample.

Swab Test Procedure (Nasal/Nasopharyngeal Swab)

1. Verify that Sofia or Sofia 2 is set to the desired Mode: WALK AWAY or READ NOW. See the “Using Sofia and Sofia 2” section for more information.

2. Dispense all of the Reagent Solution into the Reagent Tube. Swirl the Reagent Tube to dissolve its contents.

3. Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.

4. Roll the Swab head against the inside of the Reagent Tube as you remove it. Dispose of the used Swab in your biohazard waste.

5. Fill the provided Small, Clear 120 µL Fixed Volume Pipette with patient sample from the Reagent Tube.

   To fill the Fixed Volume Pipette with the patient sample:
   a) FIRMLY squeeze the top bulb.
   b) Still squeezing, place the Pipette tip into the sample.
   c) With the Pipette tip still in the sample, release pressure on bulb to fill the Pipette.

6. Firmly squeeze the top bulb to empty the contents of the Small, Clear 120 µL Fixed Volume Pipette into the Test Cassette sample well. Extra liquid in the overflow bulb is OK.

   NOTE: The Fixed Volume Pipette is designed to collect and dispense the correct amount of patient sample. Discard the Pipette in your biohazard waste.

   NOTE: Do not pour sample from the Reagent Tube. Use the provided Small, Clear 120 µL Fixed Volume Pipette.

7. Proceed to the “Using Sofia and Sofia 2” section to complete the test.
WALK AWAY/READ NOW Modes  
*Refer to the Sofia User Manual.*

Sofia may be set to two different modes (WALK AWAY and READ NOW). The procedures for each mode are described below.

**WALK AWAY Mode**

In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia. Sofia will automatically time the test development, and the results will be displayed in 15 minutes.

**READ NOW Mode**

Allow the test to develop for the FULL 15 minutes BEFORE placing it into Sofia.

The user places the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia). The user manually times this development step. The Test Cassette MUST remain on the bench for 15 minutes to get an accurate result. Then, the user inserts the Test Cassette into Sofia. In READ NOW Mode, Sofia will scan and display the test result in 1 minute.

**Warning:** Results must not be interpreted past 30 minutes after inoculation. Using the Sofia past this time may result in false results.

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**RUN TEST**

1. Input the User ID with the barcode scanner or enter the data using the key pad.

   **NOTE:** If you scan the wrong barcode, use the Arrow Keys on Sofia to re-highlight the field and simply rescan using the correct barcode. The previous one will be overwritten with the right barcode.

2. Input the Patient ID or Order # with the barcode scanner or enter the data using the key pad.

3. Press Start Test and the Sofia drawer will open.

4. Verify that the correct mode (WALK AWAY or READ NOW) has been selected. Insert the Test Cassette into the drawer. Then gently close the drawer.

5. Sofia will start automatically and display the Mode, the test results will be displayed in approximately 15 minutes. In READ NOW Mode, the test results will be displayed in 1 minute. See Sofia Interpretation of Results section.
When the test is complete, the results will be displayed on the Sofia screen. The results can be automatically printed on the integrated printer if this option is selected. Test Lines will not be visible to the naked eye.

**Results:** The Sofia screen will display results for the procedural control as being “valid or invalid.” If the control is “invalid,” retest with a new patient sample and new Test Cassette.

### Sofia Interpretation of Results

<table>
<thead>
<tr>
<th>Reader Display</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS: Positive</td>
<td>Positive Test SARS</td>
</tr>
<tr>
<td>Procedural Control: Valid</td>
<td>(SARS Antigen present)</td>
</tr>
<tr>
<td>SARS: Negative</td>
<td>Negative Test for SARS</td>
</tr>
<tr>
<td>Procedural Control: Valid</td>
<td>(no SARS antigen detected)</td>
</tr>
<tr>
<td>SARS:</td>
<td>Result Invalid</td>
</tr>
<tr>
<td>Procedural Control: Invalid</td>
<td></td>
</tr>
</tbody>
</table>

### Sofia External Quality Control *(External Positive and Negative Swabs are supplied in the kit)*

1. From the main menu, select Run QC.
2. Follow the prompts on the screen. Scan the QC Card (located on the kit box).
3. Sofia prompts the user to select the desired mode (WALK AWAY or READ NOW). Run the External Control Swabs.
4. Follow the Swab Test Procedure of this Quick Reference Instructions. First test the Positive Swab, followed by the Negative Swab.
5. After both the Positive and Negative Swabs have been run, the results will be displayed as “Passed” or “Failed.”
Using Sofia 2

WALK AWAY/READ NOW Modes

Refer to the Sofia 2 User Manual.

Sofia 2 may be set to two different modes (WALK AWAY and READ NOW). The procedures for each mode are described below.

### WALK AWAY Mode

In WALK AWAY Mode, the user immediately inserts the Test Cassette into Sofia 2. Positive and negative test results will be displayed at 15 minutes.

### READ NOW Mode

The user first places the Test Cassette onto the counter or bench top for 15 minutes (outside of Sofia 2). The user manually times this development step. The Test Cassette MUST remain on the bench for 15 minutes to get an accurate result. Then, the user inserts the Test Cassette into Sofia 2. In READ NOW Mode, Sofia 2 will scan and display the test result within 1 minute. **Warning: Results must not be interpreted past 30 minutes after inoculation. Using the Sofia past this time may result in false results.**

### RUN TEST

1. Input the User ID with the integrated barcode scanner or manually enter the data using the key pad.

   **NOTE:** If you scan the wrong barcode, re-highlight the field using the touchscreen on Sofia 2. The previous one will be overwritten with the right barcode.

2. Input the Patient ID and Order # (if applicable) with the integrated barcode scanner or manually enter the data using the key pad.

3. Verify that the correct mode (WALK AWAY or READ NOW) has been selected. Press and open the Sofia 2 drawer.

4. Insert the Test Cassette into the drawer. Then gently close the drawer.

5. Sofia 2 will start automatically and display the progress. In WALK AWAY Mode, the test results will be displayed in approximately 15 minutes. In READ NOW Mode, the test results will be displayed within 1 minute. See Sofia 2 Interpretation of Results section.
**Sofia 2 Interpretation of Results**

When the test is complete, the results will be displayed on the Sofia 2 screen. Test Lines will not be visible to the naked eye.

**Results:** The Sofia 2 screen will display results for the procedural control as being 🟢 or 🟥. If the control is 🟥, retest with a new patient sample and new Test Cassette.

<table>
<thead>
<tr>
<th>Reader Display</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS: 🟢</td>
<td>Positive Test for SARS (SARS antigen present)</td>
</tr>
<tr>
<td>Procedural Control: 🟢</td>
<td></td>
</tr>
<tr>
<td>SARS: 🟥</td>
<td>Negative Test for SARS (no SARS antigen detected)</td>
</tr>
<tr>
<td>Procedural Control: 🟥</td>
<td></td>
</tr>
<tr>
<td>SARS: 🟥</td>
<td>Result Invalid</td>
</tr>
<tr>
<td>Procedural Control: 🟥</td>
<td></td>
</tr>
</tbody>
</table>

**Sofia 2 External Quality Control (External Positive and Negative Swabs are supplied in the kit)**

1. From the main menu, select Run QC.
2. Follow the prompts on the screen. Scan the QC Card (located on the kit box).
3. Sofia 2 prompts the user to select the desired mode (WALK AWAY or READ NOW).
4. Run the External Control Swabs.
5. Follow the Swab Test procedure of this Quick Reference Instructions. First test the Positive Swab, followed by the Negative Swab.
6. After both the Positive and Negative Swabs have been run, the results will be displayed as 🟢 or 🟥.

**INTENDED USE**

The Sofia SARS Antigen FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia and Sofia 2 instrument intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The Sofia SARS Antigen FIA is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings, and proficient in performing tests using the Sofia and Sofia 2 instruments. The Sofia SARS Antigen FIA is only for use under the Food and Drug Administration’s Emergency Use Authorization.

The Sofia SARS Antigen FIA should be used with Sofia or Sofia 2.
In the USA, this test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests and at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, In the USA, - this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Reference the Package Insert for **Warnings and Precautions, Limitations, Specimen Collection and Handling, and**

**ASSISTANCE**

If the Sofia, Sofia 2 or the assay do not perform as expected, contact Quidel Technical Support 800.874.1517 (in the U.S.), 858.552.1100 (outside the U.S.), technicalsupport@quidel.com, or your local distributor.

Study the Package Insert and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.